510(k) Summary

FEB 23 2011

Astra Tech AB
Astra Tech Implant System

October 28, 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name: Astra Tech AB
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Astra Tech Implant System
Common Name:	Dental implant
Classification Regulations:	Implant, endosseous, root form Class II, 21 CFR 872.3640
Product Code:	DZE
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

The OsseoSpeed implants are intended to be used:

- to replace missing teeth in single or multiple unit applications within the mandible or maxilla
- for immediate placement in extraction sites and partially or completely healed alveolar ridge situations
- for both one- and two-stage surgical procedures

- especially well in soft bone applications where implants with other implant surface treatments may be less effective
- together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate
- together with immediate loading protocol for single-tooth restorations on implants 8 mm or longer
- with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.

DEVICE DESCRIPTION

Astra Tech Implant System implants are intended to support prosthetic devices in edentulous or partially edentulous patients to restore esthetics and chewing function. The new components of the Astra Tech Implant System included in this submission are OsseoSpeed TX implants which have a narrower tapered apex design compared to OsseoSpeed implants (K053384). They are placed using a modified drilling protocol with new conical drill sizes. The modified drilling protocol is specifically designed for soft bone applications. All other features and procedures of OsseoSpeed TX implants remain the same as those for OsseoSpeed implants.

The purpose of this submission is to add the OsseoSpeed TX implants to the present product line and expand device claims regarding primary stability of Astra Tech Implant System implants.

TESTING

Testing was performed to compare OsseoSpeed TX implants using the new soft bone drilling protocol with OsseoSpeed implants using the standard drilling protocol. Calculations also were made to determine bone to implant contact for the two implant/drilling protocol combinations. The design of the OsseoSpeed TX implants, combined with the soft bone drilling protocol, results in improved primary mechanical stability of the implant.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech AB in this Premarket Notification demonstrated that, for the purposes of FDA's regulation of medical devices, the Astra Tech Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Nobel Biocare NobelActive Internal Connection Implant cleared under K071370,
Astra Tech Astra Tech Implant System cleared under K091239, and
Astra Tech Fixture MicroThread™ OsseoSpeed™ cleared under K053384.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium conforming to ASTM F67. They encompass the same range of physical dimensions, including diameter and length of the implants. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

Astra Tech AB demonstrated that, for the purposes of FDA's regulation of medical devices, the Astra Tech Implant System is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices.

The Astra Tech Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Astra Tech AB
C/O Ms. Linda K. Schulz
Paxmed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

FEB 23 2011

Re: K101732
Trade/Device Name: Astra Tech Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 28, 2011
Received: January 28, 2011

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

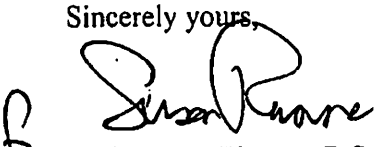
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K101732

Device Name: Astra Tech Implant System

Indications for Use:

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- to replace missing teeth in single or multiple unit applications within the mandible or maxilla
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101732